UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

IN RE: ZETIA (EZETIMIBE) ANTITRUST LITIGATION	MDL No. 2:18-md-2836
THIS DOCUMENT RELATES TO: DIRECT PURCHASER ACTIONS	

DEFENDANTS' OPPOSITION TO DIRECT PURCHASER PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

The class action device is the "exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011). The specific circumstances here do not warrant that exceptional approach.

This case is one of a growing number of pharmaceutical direct purchaser antitrust actions in which a few small entities try to use the class action device where it is not needed to rope in much larger alleged claims held by the Big 3 wholesalers: McKesson, AmerisourceBergen, and Cardinal. These three multi-billion-dollar enterprises, each with billions of dollars of supposed overcharges in connection with Zetia® and ezetimibe, could easily assert their own claims if they wanted to. But instead, the named plaintiffs here ("DPPs") seek to increase their own bargaining power by wielding the claims of giant wholesalers who are nothing like them, while the wholesalers themselves are absent from the litigation. The Third Circuit expressed concern with this very circumstance when denying certification of a direct purchaser class in another pharmaceutical antitrust action, *In re Modafinil Antitrust Litigation*, noting that the Big 3 wholesalers "can hardly be considered as candidates who need the aggregative advantages of the

class device." 837 F.3d 238, 258 (3d Cir. 2016).

While classes of direct purchasers have been certified in other direct purchaser antitrust actions, the law applicable in the Fourth Circuit and the guidance provided by *In re Modafinil*, along with the specific circumstances of this case, mean that certification is not appropriate here. First, despite an array of attempts to expand the class size—one of which this Court has already rejected—DPPs' proposed class is small, even for this type of case. After removal of purchasers that DPPs now concede should not be part of the class and purchasers from Par, who this Court has already decided cannot bring claims against Merck and Glenmark, DPPs claim a class of 42 entities. But even this number is substantially exaggerated. When corrected to comply with the law, DPPs have only 23 total class members, and it is plainly practicable to join those class members to this case.

Second, neither FWK nor RDC is an adequate class representative, and CCI is incapable of satisfying Rule 23's typicality requirement. FWK is a mere shell company, effectively controlled by DPPs' counsel. This lack of independence renders it an inadequate class representative, as the District of Massachusetts recently held. *In re Intuniv Antitrust Litig.*, 2019 WL 4645502, at *8 (D. Mass. Sept. 24, 2019). RDC's recent criminal conduct renders it unfit to serve in the trust position of a class representative. The third class representative, CCI, is subject to unique defenses because it did not even purchase generic ezetimibe until *after* filing its claims here, and does not appear to have suffered any actual injury.

Finally, common issues do not predominate over individual issues here, as required under Federal Rule of Civil Procedure 23(b)(3) to certify a damages class. If the brand-only purchasers that did not suffer any overcharges are included in the class, whether each one was actually injured will require individualized proof.

In short, DPPs simply cannot survive the "rigorous analysis" that courts must undertake to ensure that a party seeking certification has proven each Rule 23 requirement by a preponderance of the evidence. *See Wal-Mart*, 564 U.S. at 350-51. The Court should deny DPPs' motion for class certification and allow this litigation to proceed as a collection of individual or joined actions.

FACTUAL BACKGROUND

DPPs have alleged that Merck and Glenmark (collectively, "Defendants"), by entering into an entirely permissible settlement of patent litigation that involved a limited exclusive license to Glenmark to produce generic ezetimibe, violated the antitrust laws. ECF No. 740, DPP Brief in Support of Motion for Class Certification ("DPP Br.") at 4–10. Evidence developed through discovery confirms that DPPs' theory is wrong, and that there was no connection between the agreed-upon entry date in the settlement and the limited license provision that DPPs challenge as a "no-AG" commitment. Far from establishing that earlier generic entry would have occurred absent this provision, the evidence establishes that, had Merck and Glenmark not settled their dispute, Glenmark would have lost that litigation and not entered the market until later than it did under the settlement—after the expiration of Merck's exclusive rights. Indeed, shortly after the Glenmark-Merck settlement, Merck went to trial against Mylan—and won.

DPPs' allegations, while meritless, do not bear on the present motion. Here, the relevant question is whether the class that DPPs seek to represent should be certified. In furtherance of their contention that it should be, DPPs first submitted the expert declaration of Dr. Jeffrey Leitzinger. ECF No. 741-01 ("Leitzinger Class Cert. Decl."). Dr. Leitzinger opined that, based on an assumption that generic entry would have occurred as early as July 2012 if not for the conduct DPPs challenge, the delay in such competition "would cause the amounts paid by Class members for ezetimibe used to fill Zetia prescriptions to be substantially higher than otherwise, resulting in widespread overcharges." Leitzinger Class Cert. Decl. at 4. Dr. Leitzinger further

concluded that this "very likely caused each proposed Class member to pay at least some overcharge in connection with its ezetimibe purchases," and that the "aggregate overcharges" could be determined by "formulaic analysis" rather than "individualized inquiry." *Id.* at 5. [redacted] and DPPs identified the class similarly in their class certification brief. *Id.*, Ex. 8; DPP Br. at 12.

On January 13, 2020, DPPs served a damages expert report from [redacted] Declaration of Christopher D. Dusseault ("Dusseault Decl."), Ex. 1 ("[redacted] Damages Rept."). [redacted]

LEGAL STANDARD

DPPs seek certification under Federal Rule of Civil Procedure 23(a) and (b)(3), which requires proof of numerosity, commonality, typicality, adequacy of representation, predominance of common questions, and superiority of the class action device. Courts undertake a "rigorous analysis" to ensure that the party seeking certification has met its burden to prove each requirement of Rule 23 by a preponderance of the evidence. *See Wal-Mart*, 564 U.S. at 350-51; *see also Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013).

ARGUMENT

I. The Putative Class of Sophisticated, Multi-Million Dollar Businesses Is Not So Numerous as To Make Joinder Impracticable.

In the "typical class action," "hundreds or thousands of claims are aggregated in order to

ensure that the wrongdoer is held accountable and that small claims are vindicated." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 259 (3d Cir. 2016) (citation omitted). While the class need not encompass "hundreds or thousands of" members (*id.*), named plaintiffs must seek to represent a group of prospective plaintiffs that is "so numerous that traditional joinder is impractical." *Deiter v. Microsoft Corp.*, 436 F.3d 461, 466 (4th Cir. 2006); Fed. R. Civ. P. 23(a)(1). The number of prospective plaintiffs is thus not dispositive, but is the "starting point of [the] numerosity analysis." *In re Modafinil*, 837 F.3d at 250.

In the pharmaceutical industry, manufacturers who sell billions of dollars of a brand drug frequently sell directly only to a very small number of direct purchasers. Accordingly, in the context of antitrust actions involving Hatch-Waxman Act settlements, plaintiffs seeking to represent classes of direct purchasers have been forced to stretch the bounds of numerosity. Rather than "hundreds or thousands of claims," most or all of which are "small claims," *In re Modafinil*, 837 F.3d at 259, plaintiffs in such cases, like DPPs here, seek to represent dozens of entities (or fewer), most of whom have seek multi-million dollar damages. In an effort to satisfy numerosity, DPPs consistently find themselves relying on strained analysis to include as class members purchasers who are already pursuing their own suits; purchasers who have no plausible claim for damages; and wholly owned subsidiaries of other class members that plainly would not be impracticable to join. Indeed, here, DPPs first tried to include *indirect* purchasers who purchased generic ezetimibe from Par, apparently in an attempt to distract from the challenges that the structure of the pharmaceutical industry can present to demonstrating numerosity.

In recent years, suspicion of this distortion of the class action device has grown in cases where the number of class members is on the lower end of the range. In 2016, the Third Circuit vacated the class certification of a class of 22 direct purchasers of the drug Modafinil, observing

that "the judges in the majority have never seen a class action where three class members, each with billions of dollars at stake and close to 100% of the total value of class claims between them, have been allowed to sit on the sidelines as unnamed class members," *In re Modafinil*, 837 F.3d at 259, a description that would fully apply to this class action as well. On remand, the Eastern District of Pennsylvania denied class certification. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2017 WL 3705715 (E.D. Pa. Aug. 28, 2017). The Northern District of Georgia more recently echoed the concerns of *In re Modafinil*, finding the class insufficiently numerous where the plaintiffs proposed a class of 33 members, a number the court assumed *arguendo* was correct. *In re Androgel Antitrust Litig.*, 2018 WL 3424612 (N.D. Ga. July 16, 2018).

Generally, courts hold that numerosity does not exist where a class has fewer than 20 members, that it is a fact-specific inquiry where between 20 and 40 members exist, and that there is a presumption of numerosity when there are more than 40 class members. *In re Modafinil*, 837 F.3d at 249-50. But DPPs' own authority reflects that courts have rarely certified classes of fewer than 30 members in this context, and DPPs cite no examples of courts finding numerosity satisfied since *In re Modafinil* with fewer than 32 members, the size of the class this Court certified in *American Sales Co., LLC v. Pfizer, Inc.*, 2017 WL 3669604 (E.D. Va. July 28, 2017). *See* DPP Br. 12 n.50. In comparison to *Pfizer*, the prospective class members here have greater incentive to sue and the MDL ensures that judicial economy is served without a class. *See infra* Section I.B.

Nonetheless, DPPs ask this Court to certify a class that, properly considered, has at most *twenty-three* purchasers. And since two of those 23 are already named plaintiffs,[1] that requires joining only 21 additional plaintiffs to this case. Those purchasers are capable of joining litigation,

[1] Named plaintiff CCI should be excluded due to lack of injury, *see* Section I.A.6, so is not included in the 23 prospective class members.

and, according to the DPPs' theory, the vast majority have millions—or even *billions*—of dollars at stake. This Court should follow the reasoning of *In re Modafinil* and conclude that joinder is not impracticable in these circumstances. DPPs have thus failed to demonstrate numerosity.

A. The Class Here Has At Most Twenty-Three Members.

1. Five Putative Class Members Should Be Excluded Because DPPs No Longer Claim Those Plaintiffs Paid Overcharges.

Although DPPs proposed a class of 70 in their motion for class certification (DPP Br. at 12), [redacted]. DPPs have moved to modify their proposed class definition to account for the new date and smaller class. *See* ECF No. 813. Accordingly, Defendants address [redacted] most up-to-date claim as to the number of class members and begin with a putative class of 65 members.[2]

2. [redacted]

As this Court is aware, DPPs amended their complaint to include purchasers from Par as prospective members of the direct purchaser class, and those purchasers are included in DPPs'

[2] To the extent DPPs later change the class definition to again include the five removed class members, Defendants reserve the right to argue that those class members should be excluded on other grounds, including because several did not buy Zetia® or generic ezetimibe during the class period and/or based on the statute of limitations.

proposed class definition. ECF No. 253-1. However, this Court properly held that DPPs "are barred from pursuing claims against Merck and Glenmark for damages resulting from their purchases of ezetimibe from Par, because they were not direct purchasers from Merck or Glenmark with respect to those purchases." *In re Zetia (Ezetimibe) Antitrust Litig.*, 2019 WL 6977405, at *7 (E.D. Va. Dec. 20, 2019). [redacted][3] Under the Court's ruling on Defendants' motion to dismiss, these entities cannot be counted in the direct purchaser class and must be excluded for purposes of numerosity, as DPPs appear to recognize in their class certification brief.[4] DPP Br. 12 n.46 (acknowledging that the Court's ruling on the Report and Recommendation "may alter the composition of the direct purchaser class"). Accordingly, there can be no serious dispute that, under the Court's ruling, the class can have a maximum of 42 members.

3. Ten Putative Class Members Are Already Parties to Litigation in This Court, Such that an Inquiry Into the Practicability of Joining Those Entities Is Unnecessary.

In determining whether joinder is practicable, the Fourth Circuit has instructed courts to consider whether the size or the prospective class would "make impracticable a joinder of those not already plaintiffs in the action." *Roman v. ESB, Inc.*, 550 F.2d 1343, 1348 (4th Cir. 1976) (en

[3] [redacted]

[4] [redacted]

banc). That is, if a suit is already proceeding in an orderly fashion with multiple plaintiffs, the question is whether it would be impracticable to add the remaining plaintiffs; existing plaintiffs need not be joined. *Id.* In *Roman* itself, the Court affirmed a refusal to certify a 53-member class because 44 people in the class had already sued. *Id.* at 1348. Since the Court calculated that joinder of all plaintiffs "would have meant joining only 11 additional persons,"[5] it held that the district court's decision that such joinder was practicable and numerosity was not present was "so apparently correct as to require no discussion." *Id.* at 1348-49. Here, ten plaintiffs have already brought suit—3 named plaintiffs in the DPPs' action, and 7 retailer plaintiffs who have brought their own suits. Accordingly, those 10 plaintiffs should not be considered in calculating the practicability of joining absent class members.

Even if the three named plaintiffs in the direct purchaser suit are counted for purposes of the practicability of joinder, the seven retailer plaintiffs have made clear their intent to proceed independently and should not be used to inflate the size of the class. The retailer plaintiffs will be suing separately regardless of whether a class is certified; treating those plaintiffs as class members whose separate suits can be avoided through certification ignores this reality. Cf. *King Drug Co.*, 2017 WL 3705715, at *2 (noting that "Retailer Plaintiffs," a group including the same retailers that have sued in this case, had previously opted out of class action settlements in that case and were "excluded from the [litigation] Class"). The Court should thus disregard the following 7 entities when considering whether the numerosity standard is met and joinder is practicable: CVS, Rite Aid Corp., Rite Aid Hdqtrs. Corp., Walgreen, Kroger, Albertsons, and H-E-B Grocery. That reduces the class to, at most, 35 entities.

[5] The court in *Roman* appears to have miscalculated how many additional persons needed to be added to 44 named plaintiffs to include all 53 affected individuals as 11 instead of 9, a difference that was not material to any question before it.

4. The Litigation Decisions of Six Additional Putative Class Members Are Controlled by Other Class Members.

[redacted] In determining whether joinder is practicable, this Court should disregard any entity that is a subsidiary of another putative class member because adding two aligned companies with the same ownership, which will likely have the same counsel and decision makers, is necessarily more practicable than joining two independent entities. It is DPPs' burden to demonstrate why joinder of a parent and its subsidiary is any different in practicability than adding the parent alone, and DPPs have failed to do so.

Notably, DPPs concede that disregarding subsidiaries is appropriate in at least some circumstances. DPPs instructed their expert witness, [redacted]

On the facts of this case, disregarding subsidiaries is proper to determine whether joinder is practicable. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 296 F.R.D. 47, 51 (D. Mass.

[redacted]

2013) (adopting defendant's number of class members, "which account[ed] for the consolidation of two entities with their parent corporations"); *Meijer, Inc. v. Warner Chilcott Holdings Co. III*, 246 F.R.D. 293, 306 n.13 (D.D.C. 2007) (noting that Dr. Leitzinger "arrived at the estimated thirty putative class members by [among other things] accounting for common ownership of parent companies and their affiliates and subsidiaries").

Although some courts have permitted subsidiaries to be considered separately for purposes of numerosity, a practical consideration of the practicability of joinder does not support that approach. In *Pfizer*, this Court concluded that subsidiaries should be counted separately based on the conclusion that subsidiaries are akin to partial assignees, which *In re Modafinil* said should be treated as independent entities. *Pfizer*, 2017 WL 3669604, at *8. But partial assignees and subsidiaries are not analogous for purposes of the practicability of joinder. Partial assignees may be independent companies with independent decision makers, such that joining a partial assignee puts precisely the same marginal additional burden on the courts or the efficiency of the case as joining a third party bringing its own claim. In contrast, joining both a parent and a subsidiary to a case would necessarily be *less burdensome* than adding two independent companies, due to the common ownership. Regardless of whether the class members made distinct *purchases*, on the issue of *joinder*, the practicability of adding two related entities is more analogous to joining one new entity than two independent ones.

Excluding the six subsidiaries to avoid double-counting reduces the class by an additional six entities, for a total of 29 putative class members.

5. Two Additional Putative Class Members Are Unlikely To Have Suffered Any Injury Because They Purchased Branded Zetia® Only And Would Not Have Received Higher Discounts After Generic Entry.

DPPs' theory of injury, advanced by [redacted], relies on several assumptions. [redacted]

[redacted]

[7] [redacted]

[redacted] In *Pfizer*, this Court declined to exclude brand-only purchasers who purchased Celebrex during the period in which generic entry was allegedly delayed. *Pfizer*, 2017 WL 3669604, at *9. However, the Court relied on the plaintiffs' proof "that brand-name Celebrex decreased in price significantly following generic entry." *Id*. [redacted], *Pfizer* is distinguishable on this point.

At a minimum, the prospective claims of these two class members cannot be considered as part of a class because Dr. Leitzinger's supposed classwide proof—which relies on averages to presume that all class members would have paid overcharges—cannot replace an individualized inquiry into whether these brand-only purchasers would *actually* have purchased generic or received higher discounts for Zetia® absent the challenged conduct. *See In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 343 (E.D. Mich. 2001) (although "there is no need for individual analysis of switching behavior as to" putative class members who bought both brand and generic, "[t]he same cannot be said for those consumers who do not switch and who remain brand-loyal"); *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 693 (S.D. Fla. 2004) (excluding brand loyalists from a class where there was no evidence regarding whether those entities were injured); *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 230 (E.D. Pa. 2012) (similar). Accordingly, exclusion of these entities reduces the total number of putative class members to 27.

6. [redacted]

[redacted]

As with the brand loyalists discussed above, the necessity of individual inquiry into the facts surrounding the miniscule number of purchases of these prospective class members would be necessary to even speculate as to whether they paid overcharges. Their claims therefore cannot be resolved by classwide proof and they should be excluded from the class. *See In re Flonase*, 284 F.R.D. at 230; *In re Terazosin Hydrochloride*, 220 F.R.D. at 693; *In re Cardizem CD*, 200 F.R.D. at 343. Moreover, because it appears likely that these entities were not injured, they cannot be included in any class, reducing the class to 23 members. *See* EPP Opp. Br. at 15 & n.11.

7. [redacted]

In his damages report, [redacted]

* * * * *

Because only 23 plaintiffs (including two named plaintiffs in the DPP class action) remain for potential certification as a class—barely more than the presumptive bare minimum for class certification—class certification here depends on the specific circumstances of the case. However, even if this Court did not accept all of Defendants' arguments, the plaintiffs, which only number 42 putative class members after eliminating the Par-only purchasers, have not met their burden of proving that the class should be certified.[8]

B. DPPs Have Not Met Their Burden of Showing Joinder Is Impracticable on These Facts.

It is plainly practicable to join 21 additional class members to this litigation. *Kennedy v. Virginia Polytechnic Inst. & State Univ*., 2010 WL 3743642, at *3 (W.D. Va. Sept. 23, 2010) ("A nationwide survey of federal court decisions signals that it is exceedingly rare to certify classes with less than 25 members."); *see also Mitchell v. Conseco Life Ins. Co.*, 2013 WL 5372776, at *6 (D.S.C. Sept. 24, 2013) (same). The Third Circuit's decision in *In re Modafinil* and this Court's recent decision in *American Sales Company, LLC v. Pfizer* provide extensive guidance in determining whether DPPs have met their burden of demonstrating numerosity in the specific context at issue here (i.e., direct purchaser pharmaceutical antitrust action). Those and other cases compel the conclusion that DPPs have not met that burden.

The inquiry into numerosity "calls for an inherently fact-based analysis that requires a district court judge to 'take into account the context of the particular case.'" *In re Modafinil*, 837 F.3d at 249. Although the framework was developed outside of the unique context of this type of pharmaceutical class action, courts commonly observe that "'if the named plaintiff demonstrates

[8] To aid the Court's review, Merck attaches [redacted] as Exhibit 15 to the Dusseault Declaration.

that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met.'" *Id*. at 249-50; *see also Pfizer*, 2017 WL 3669604, *9. *But see Roman*, 550 F.2d at 1348 (affirming denial of certification of 53-person putative class). On the other hand, "[a]s a general guideline . . . a class that encompasses fewer than 20 members will likely not be certified absent other indications of impracticability of joinder." *In re Modafinil*, 837 F.3d at 250. Treatment of classes with "between 21 and 40 members" varies according to "the circumstances of each particular case." *Id*. (quoting 5 James Wm. Moore, et al., *Moore's Federal Practice* § 23.22).[9]

The circumstances of this case, like other direct purchaser antitrust actions in the pharmaceutical context, make joinder practicable at higher numbers than in some other contexts. In *In re Modafinil*, the court identified as relevant factors "judicial economy, the claimants' ability and motivation to litigate as joined plaintiffs, the financial resources of class members, the geographic dispersion of class members, the ability to identify future claimants, and whether the claims are for injunctive relief or for damages." 837 F.3d at 253; *see also Pfizer*, 2017 WL 3669604, at *9. These factors are relevant to whether a case should be litigated as "a class action versus joinder of all interested parties." *In re Modafinil*, 837 F.3d at 253. Among the factors, "judicial economy and the ability to litigate as joined parties are of primary importance." *Id*.

Judicial economy. Judicial economy favors certification where "the class action mechanism is *substantially* more efficient than joinder of all parties." *In re Modafinil*, 837 F.3d at 254 (emphasis added). This factor "looks to the administrative burden that multiple or aggregate

[9] Where, for example, class members were individuals who faced a risk of retaliation for joining an anti-discrimination lawsuit and lacked sufficient motivation to join a suit, the Fourth Circuit affirmed certification of an 18-member class. *Cypress v. Newport News Gen. & Nonsectarian Hosp. Ass'n*, 375 F.2d 648, 653 (4th Cir. 1967). That DPPs invoke *Cypress* as they seek certification of an only slightly larger class of multi-million and multi-billion dollar corporations reflects their lack of attention to the circumstances of this case. DPP Br. at 12.

claims place upon the courts." *Id.* The "late stage of litigation and the sunk costs already incurred" are not relevant factors in this inquiry, because treating them as such would "place a thumb on the scale in favor of a numerosity finding for no reason other than the fact that the complex nature of a case resulted in the class certification decision being deferred for years." *Id*. at 255.

Here, joining the additional potential class members to one of the ongoing cases in the MDL would be just as efficient as proceeding with a class. In particular, as in *In re Modafinil*, "Plaintiffs have been using the same experts," and "[i]t is not clear that there would be a need for that to change merely because Plaintiffs would be joined as individual parties instead of moving forward as a class." 837 F.3d at 256. *See also King Drug Co.*, 2017 WL 3705715, at *7 (defendant "convincingly responds that throughout this case the various plaintiff groups have engaged in a multitude of cost and resource sharing tactics").

Moreover, this case reflects centralization by the MDL panel, which further ensures efficiency and avoids the risk of duplicative actions or inconsistent liability. Enormous amounts of discovery have already been undertaken, and DPPs have not suggested that any other discovery would be necessary if parties were joined; indeed, the only discovery that may be necessary would be that into individualized issues that have been necessarily underdeveloped in the absence of the presence of each potential class member. *See infra* Section III; *In re Modafinil*, 837 F.3d at 256 ("If the members all opted to join the case as individual plaintiffs, the District Court could, in its discretion, limit discovery where [it] 'is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive.'") (quoting Fed. R. Civ. P. 26(b)(2)(C)(i)). The potential judicial economy interest that this Court found favored class certification in *Pfizer*—allowing common evidence on "the overlapping elements of the class members' claims," 2017 WL 3669604, at *10—could be achieved by consolidating cases

raising those issues, a matter that is facilitated by the fact that this case, unlike *Pfizer*, already is an MDL. Moreover, the fact that a significant amount of the claimed damages belongs to plaintiffs who have *already* chosen to pursue their own litigation instead of aligning with the named plaintiffs ensures that all claims by direct purchasers will not be litigated in a single case, regardless of whether a class is certified. *See* 1 Joseph M. McLaughlin, *McLaughlin on Class Actions* § 5:64 (16th ed. 2019) (where "significant opt-outs seem likely, class certification makes little sense, as the efficiencies achieved by class litigation vanish").[10]

Ability and motivation to litigate as joined plaintiffs. The ability and motivation of potential class members here to pursue their claims by joinder exceeds that present in *Pfizer*. Evaluation of this issue "involves an examination of the stakes at issue for the individual claims and the complexity of the litigation, which will typically correlate with the costs of pursuing those claims." *In re Modafinil*, 837 F.3d at 257. Here, as in *In re Modafinil*, "three class members, none of whom are named plaintiffs, each have claims estimated at over $1 billion—even before the trebling of damages." *Id*. at 258. Plainly, these class members (or their assignees) have every incentive to pursue this case fully if they have a meritorious claim, even if other joined plaintiffs contribute relatively less. Indeed, after the court denied certification on numerosity grounds in *In re Androgel*, 2018 WL 3424612, at *2-4, a dozen of the same direct purchasers that are potential class members here filed a joint antitrust complaint to raise their reverse-payment settlement arguments. *King Drug Co. of Florence v. Abbott Labs*., 2020 WL 60108 (E.D. Pa. Jan. 6, 2020).

Moreover, while in *In re Modafinil*, the Court found it significant that 13 of the other 19

[10] In similar cases, the same retailer plaintiff have opted out of certified classes. *See, e.g.*, *In re Solodyn Antitrust Litig.*, 2018 WL 7075881, at *1 (D. Mass. July 18, 2018); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, 2011 WL 13097266, at *1 (D. Del. Nov. 16, 2011); *In re Neurontin Antitrust Litig.*, 2013 WL 4042460, at *1 n.2 (D.N.J. Aug. 8, 2013).

class members (68%) had claims greater than $1 million, here [redacted] As in *In re Modafinil*, even if it were impracticable for those with claims under $1 million to litigate alone, "there has been no showing that it would be uneconomical for these six class members to be individually joined as parties in a traditional lawsuit." 837 F.3d at 259. *See also Stoudt v. E.F. Hutton & Co.*, 121 F.R.D. 36, 38 (S.D.N.Y. 1988) ("Rule [23] was not designed to permit large claimants, who are fully capable of proceeding on their own, to strengthen their bargaining position by threatening their adversaries with the prospect of class-wide relief and large attorney fee awards."). This case has a higher percentage of $1 million claimants than other cases that denied certification on this basis. *See King Drug Co. of Florence, Inc.*, 2017 WL 3705715, at *7, 9–10; *In re Androgel*, 2018 WL 3424612, at *2.

This Court's reasoning in *Pfizer* likewise disfavors certification. In *Pfizer*, this Court observed that "the majority of the proposed class members have negative value claims (i.e., the expenses, including expert fees, exceed their possible recovery)." 2017 WL 3669604, at *10. [redacted] Moreover, in *Pfizer*, this Court considered evidence that the line for a "negative-value case" occurred at about $2.4 million, a number based on the plaintiffs' assumption that each plaintiff would have to pay *all* expert costs, an assumption that does not account for the efficiencies that would be available from joinder. 2017 WL 3669604, at *10 (citing Tr. of Hr'g on Mot. to Certify Class 114:2-25, 115:1-4 (ECF No. 3[56])). DPPs present no such evidence here. [redacted]

Even if joining the litigation were uneconomical for a small portion of the putative class, certifying a class so that these few small claimants did not have to join is not required, and would cause more harm than possible good. The Third Circuit cautioned that class certification may still be inappropriate where it would be uneconomical for a small number of class members to join the litigation, *In re Modafinil*, 837 F.3d at 259, and the Court in *Androgel* reached precisely that holding, *In re Androgel*, 2018 WL 3424612, at *3 ("[E]ven if there were still some small number of claims that would be uneconomical to bring, in light of the other factors at play, the Court still finds that a class action would be inappropriate here."). [redacted] Yet class certification poses a large potential harm to Defendants since it will arm class representatives' counsel with the ability to pressure a settlement by wielding the bargaining power of the allegedly billion-dollar-claims held by massive companies that have chosen not to participate in this case.

Finally, DPPs speculate that some wholesalers might fear retaliation from Merck if they sue. DPP Br. at 13. But DPPs have offered no evidence that such retaliation is a realistic risk. "Fail[ing] to offer any concrete evidence" renders concern about retaliation not probative. *King Drug Co.*, 2017 WL 3705715, at *10; *see also In re Androgel*, 2018 WL 3424612, at *4 (denying certification despite plaintiffs raising same reprisal speculation, and reasoning that "although a class action would shield smaller Plaintiffs from discovery, it is not as if it would shield their identity. The Defendants would still know they were opposing them in litigation.").

Financial resources of class members. The financial resources of class members similarly

favors joinder over certification here. [redacted] This is not a case of small or individual players unable to ascertain how to file a lawsuit to be joined to this case, or unable to afford doing so. This is particularly true given that, as courts have recognized, cases like this often proceed on a contingent fee arrangement that frees smaller plaintiffs from the burden of upfront payment. *See King Drug*, 2017 WL 3705715, at *10 ("The reality of contingent representation significantly undercuts Direct Purchasers' argument regarding litigation costs . . . .").

Geographic dispersion. The geographic dispersion of class members would "weigh[] slightly in favor of class certification" here, *King Drug Co.*, 2017 WL 3705715, at *11, but this factor is mitigated by the size of the claims. Moreover, DPPs assert that geographic dispersion presents a risk of individual suits "spread across the country in disparate courts," DPP Br. at 13, but that risk is mitigated by the fact that the MDL panel has centralized the cases in this Court. Notably, DPPs offer no evidence that any putative class members would be unwilling to join a suit in this Court, and indeed, the plaintiffs that have filed complaints in the Zetia® MDL are themselves geographically dispersed, yet filed and have litigated in this district.

Other factors. Finally, the last two factors are undisputed here. DPPs certainly seek damages, and all claimants are identified because the universe of direct purchasers is known. *See King Drug Co.*, 2017 WL 3705715, at *11.

In short, the circumstances of this case make joinder practicable at higher numbers, yet DPPs are seeking to bring as few as 21 additional entities into this case through certification. In this circumstance, joinder is not impracticable and numerosity does not exist.

II. Each of the Named Representatives Fails Either Adequacy or Typicality.

A. FWK and RDC Are Not Adequate Class Representatives.

Not only is the number of potential class members prohibitively small, but FWK and RDC

are not suitable class representatives. Rule 23(a)(4) requires DPPs to establish by a preponderance of the evidence that "the representative parties will fairly and adequately protect the interests of the class." *Oakley v. Verizon Commc'ns Inc.*, 2012 WL 335657, at *10 (S.D.N.Y. Feb. 1, 2012); *see also In re NII Holdings, Inc. Sec. Litig.*, 311 F.R.D. 401, 405 (E.D. Va. 2015). To be adequate, a class representative "must be part of the class and possess the same interest and suffer the same injury as the class members." *In re NII Holdings*, 311 F.R.D. at 407 (quoting *Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 156 (1982)). Thus, the "adequacy inquiry" can be distilled to two issues: (1) has plaintiff "demonstrated the requisite level of knowledge and control of the litigation to ensure" vigorous prosecution; and (2) has plaintiff demonstrated the "requisite credibility to ensure that he will act as an appropriate fiduciary" for the class. *Shiring v. Tier Techs., Inc.*, 244 F.R.D. 307, 315–16 (E.D. Va. 2007). Adequacy "is for the plaintiffs to demonstrate; it is not up to defendants to disprove the presumption of adequacy." *Id.* (citation omitted).

Class representatives are fiduciaries, and absent class members are "dependent upon [class representatives'] diligence, wisdom and integrity." *Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 549 (1949). The weighty responsibility of class representation has compelled courts to scrutinize and reject proposed class representatives where there was even the "possibility of inadequacy and the appearance of impropriety." *In re IMAX Sec. Litig.*, 272 F.R.D. 138, 155, 157 (S.D.N.Y. 2010). As discussed below, neither FWK nor RDC meets the standard necessary to be a class representative in this action.

1. FWK Is Inadequate Because It Is a Mere Shell Company—a Litigation Vehicle That Lacks Independence from Class Counsel

It is fundamental that "[a] class representative must not simply lend his name to a suit controlled entirely by the class attorney, as the class is entitled to an adequate representative, one who will check the otherwise unfettered discretion of counsel in prosecuting the suit." *In re*

Monster Worldwide, Inc. Sec. Litig., 251 F.R.D. 132, 135 (S.D.N.Y. 2008) (citation and quotation marks omitted). A class representative cannot simply be "the willing pawn of counsel." *Id*. at 136. Thus a "key element" in determining the adequacy of a class representative "is the relationship between the class representative and class counsel." *IMAX*, 272 F.R.D. at 155 (citations omitted). This is because a "close" relationship between class counsel and a class representative creates a risk—or at least the "appearance"—that the class representative may be "more interested in maximizing the return to his counsel than in aggressively presenting the proposed class' action." *Id*. at 155-57; *see also Spotswood v. Hertz Corp.*, 2019 WL 498822, at *13 (D. Md. Feb. 7, 2019) (finding representative inadequate "[g]iven the close ties" between plaintiff and counsel where plaintiff "might be motivated to maximize" attorney's fees).

In a recent decision, the District of Massachusetts court held that FWK was not an adequate class representative in an antitrust pharmaceutical case due to the "close relationship between FWK and class counsel and the Court's assessment that FWK is not engaged in meaningful supervision of this case." *In re Intuniv Antitrust Litig.*, 2019 WL 4645502, at *8 (D. Mass. Sept. 24, 2019). Precisely the same issues attend FWK here. [redacted]

Not only does FWK lack any real operations, but it was created by attorneys from Vanek, Vickers & Masini P.C., and Sperling & Slater, P.C., class counsel in this litigation, to facilitate those law firms' interests. *In re Intuniv*, 2019 WL 4645502, at *7. When the wholesaler Frank

W. Kerr declared bankruptcy in 2016, attorneys at those firms conceived of a strategy to purchase Kerr's antitrust litigation rights for the opportunity to continue representing those rights in Kerr's absence. *Id.* [redacted] *In re Intuniv*, 2019 WL 4645502, at *7. [redacted] The use of [redacted] in class action litigation has been criticized. *See Ark. Teacher Ret. Sys. v. State St. Bank & Tr. Co.*, 2018 WL 3216012, at *1 (D. Mass. June 28, 2018); Exs. 9–10. Courts have also expressed concern where funds designated for attorneys' fees are directed to individuals closely associated with a supposedly independent class representative. *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430,

566 (S.D.N.Y. 2018).

On these facts, the "close relationship" between FWK and class counsel in this action exceeds the level of entanglement that courts have found renders a class representative inadequate. *See, e.g.*, *In re Intuniv*, 2019 WL 4645502, at *8; *Spotswood*, 2019 WL 498822, at *13. As the Court observed in *In re Intuniv*, this does not mean that there is "impropriety in the action of FWK or class counsel," only that "their close business and personal relationship creates significant doubts about whether FWK could or would engage in an arm's length discussion about attorney fees with class counsel." 2019 WL 4645502, at *8; *see also LIBOR*, 299 F. Supp. 3d at 566.

DPPs do not dispute the facts on which the *In re Intuniv* court relied, but assert that Mr. Kolschowsky manages FWK, therefore making FWK independent. DPP Br. at 19. But that independence is merely surface-level. [redacted], DPPs' assertion that [redacted] (*id.* at 19) is unrealistic. Moreover, Mr. Kolschowsky's testimony that [redacted] (*id.* at 20) does not change the "close relationship between FWK and class counsel." *In re Intuniv*, 2019 WL 4645502, at *8. Nor does [redacted] meet FWK's burden of "demonstrat[ing] that [FWK], rather than [its] counsel, is in control of the litigation." *Shiring*, 244 F.R.D. at 316. Because FWK will not be a true check on class counsel, it is not an adequate class representative.

2. RDC's Recent Criminal Conduct and Ongoing Monitorship Render It an Inadequate Class Representative.

It is well settled that, as a fiduciary, a plaintiff is an inadequate class representative if it lacks the "honesty and integrity" required to effectively represent the class. *Shiring*, 244 F.R.D. at 317; *see also Deiter v. Microsoft Corp.*, 436 F.3d 461, 466 (4th Cir. 2006) (representatives are given "trust responsibility" under Rule 23). In this regard, courts routinely consider

"investigations, charges, and determinations of wrongdoing in deciding whether a proposed class representative will adequately represent a putative class." *In re Marsh & McLennan Cos. Sec. Litig.*, 2008 WL 2941215, at *6 (S.D.N.Y. July 30, 2008); *Milbourne v. JRK Residential Am., LLC*, 2014 WL 5529731, at *8 (E.D. Va. Oct. 31, 2014) ("A criminal record can be germane to this [adequacy] inquiry."). Crimes involving fraud or dishonesty are especially problematic because the class representative is placed in a position of trust with respect to other class members, and courts try to ensure that untrustworthy plaintiffs cannot "cast a shadow over" the rest of the class. *Kline v. Wolf*, 702 F.2d 400, 403 (2d Cir. 1983); *see also Xianglin Shi v. Sina Corp.*, 2005 WL 1561438, at *5 (S.D.N.Y. July 1, 2005) (finding a proposed lead plaintiff inadequate due to felony conviction for providing false information to financial institution).

On April 22, 2019, well after this Court concluded in *Pfizer* that RDC was an adequate class representative and after the bulk of cases on which DPPs rely, RDC and two of its top executives were charged with the first-ever felonies against a pharmaceutical distributor and its leadership for their role in the opioid epidemic. Dusseault Decl., Ex. 11 at 1–2. RDC was charged with felony conspiracy to distribute controlled substances, felony conspiracy to defraud the United States, and felony willful failure to file suspicious order reports with the Drug Enforcement Agency ("DEA"). *Id.* at 2. Two former RDC executives—CEO Laurence Doud III and Chief Compliance Officer William Pietruszewski—were charged with narcotics conspiracy and conspiracy to defraud the United States. *Id*. at 2-3. RDC entered into a Deferred Prosecution Agreement ("DPA") in which RDC admitted that it perpetrated a fraudulent scheme against the United States for years in order to financially benefit itself. Dusseault Decl., Ex. 12. RDC agreed to pay a $20 million fine and submit to three years of independent supervision. *Id.* ¶¶ 3, 11, 27–29.

In the DPA [redacted],[11] RDC admitted to a record of egregious misconduct and dishonesty in which RDC prioritized profits over both its legal obligations and basic honesty. To pull off its felonious fraud, RDC and its executives used "deceit, craft, trickery, and dishonest means." Dusseault Decl., Ex. 13 ¶ 38. The company and its executives repeatedly "made material misrepresentations to the DEA." *See* Dusseault Decl., Ex. 12 at Ex. B ¶ 24. [redacted]; Ex. 13 ¶ 24–27, 30; Ex. 12 at Ex. B ¶¶ 16, 19, Ex. C ¶¶ 21, 23–24, 29.

The facts set forth in the DPA render RDC an inadequate representative. First, the Court should not appoint an entity to a position of trust over absent class members when only months earlier it admitted to perpetrating a scheme of "deceit, craft, trickery, and dishonest[y]." Dusseault Decl., Ex. 12 at Ex. B ¶ 38; Ex. 13 ¶ 38. Having admitted to prioritizing its own profit over its legal obligations *for years*, RDC is ill suited to act as the fiduciary of absent class members in this case. *See In re Proxima Corp. Sec. Litig*., 1994 WL 374306, at *17 (S.D. Cal. May 3, 1994) (class representative inadequate because it "admitted that [it] committed fraud and now seeks to prosecute it"). Even assuming that RDC has purged each one of its deceitful actors, RDC is still

[11] In September 2019, RDC moved for a protective order prohibiting Defendants from questioning RDC's 30(b)(6) designee regarding RDC's criminal conduct on the ground that it had offered testimony on that subject in a May 2019 deposition in another antitrust class action, *In re Restasis*, No. 18-md-2819 (E.D.N.Y.). ECF Nos. 615, 616. On October 8, 2019, the Court entered an order prohibiting Defendants from questioning RDC about matters addressed in its previous testimony and providing that Defendants could rely on RDC's "previous sworn testimony as if it had been given again in these proceedings." ECF No. 691.

subject to ongoing and intrusive monitoring, which will occupy its attention and resources. *In re Network Assocs., Inc. Sec. Litig.*, 76 F. Supp. 2d 1017, 1029 (N.D. Cal. 1999) (finding inadequate an entity "otherwise preoccupied with its own legal problems").

B. CCI Has Atypical Claims Because It Purchased a Tiny Quantity of Generic Ezetimibe

In addition to the flaws that attend FWK and RDC, "the presence of a unique defense . . . may be an additional basis for holding that plaintiff is not an adequate representative." *Shiring*, 244 F.R.D. at 315 n.13. For example, *LIBOR* held that a plaintiff had atypical claims from the class because it was subject to the unique defense that its claims were invalidly assigned to it. 299 F. Supp. 3d at 550. "[T]o defeat class certification, it is not necessary that the [unique] defense asserted against the putative class representative ultimately succeed . . . . the presence of even *an arguable defense* peculiar to the named plaintiff . . . may destroy the required typicality." *Shiring*, 244 F.R.D. at 313 (citations and quotations omitted) (unique defenses defeated typicality).

CCI fails the typicality requirement because it is subject to a unique defense. [redacted] Accordingly, CCI is likely an uninjured, brand-only purchaser that is not appropriate to represent a class including massive wholesalers that purchased billions of dollars of Zetia® and generic ezetimibe. Given these facts, CCI cannot satisfy typicality or adequacy. *See Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc.*, 502 F.3d

91, 103-04 (2d Cir. 2007) ("If, for example, either [an assignee] is not sufficiently 'aligned in interest with the represented group' or has insufficient knowledge or access to information, it may not qualify" as an adequate class representative); *Spotswood*, 2019 WL 498822, at *12 (class representative was atypical and inadequate where he did not suffer economic injury relating to the claim and was subject to unique defenses from his refusal to pay the fees at issue).

III. Common Issues Do Not Predominate Over Individual Issues.

Defendants do not dispute that some common issues exist in this case. However, to the extent that uninjured or only potentially injured plaintiffs are included as potential class members, individual issues defeat predominance under Rule 23(b)(3).

For a significant number of the putative class members DPPs propose to include in the class, individual characteristics preclude application of Dr. Leitzinger's presumption of classwide overcharge. In particular, [redacted] For example, if an entity ordered a handful of pills for research purposes for which it preferred to have the brand drug, it would never have made generic purchases, and its small quantity may well mean it would never have gotten a discount on Zetia®. Accordingly, whether those entities would have saved money if earlier generic entry had occurred requires individual inquiry. *See id*.

In contrast to the putative EPP class, the entities that present potential issues in this regard can be easily identified and excluded from the class, fatally undermining any finding of numerosity. *Cf.* EPP Br. at 24–25. But to the extent these entities are left in the class, an equally serious impediment to class certification exists. Even if the prospective class, contrary to all the reasons in Section I.A, were held to include all 42 direct purchasers, that would mean at least 19%

of the class presented individual issues with respect to whether they actually suffered harm. Dr. Leitzinger's aggregate calculation glosses over this fact because a handful of plaintiffs experienced the overwhelming majority of the claimed overcharges. Leitzinger Class Cert. Decl. at 23–24. But that underscores the impropriety of certification, by highlighting that DPPs are pulling uninjured entities with no claims into a case simply to manufacture a class, thereby depriving Defendants of the due process right to prove that those entities never suffered harm. *See In re Asacol Antitrust Litig.*, 907 F.3d 42, 52–53, 56-58 (1st Cir. 2018).

CONCLUSION

For the reasons stated herein, DPPs' Motion for Class Certification should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 20, 2020, electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will automatically email notification of such filing to all counsel of record.

DATED: January 20, 2020

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